



K080738

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Ormond Beach, FL 32176
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PREMARKET SUMMARY
(As Required By 21 CFR 807393)

MAY 18 2008

Contact person: Claude Berthoin
Video Dental Concepts, Inc.
110 East Granada Boulevard
Suite 207
Ormond Beach, FL 32176
Phone: 800-323-2690

Alternate contact: Sue Williams

General Information

Proprietary or Trade Name: Dentron Sensor
Common/Usual Name: Dental Image Management System
Classification & Regulation Number: Class II, CCD area image sensor; MUH, MQB;
892.1650

Reason for Premarket Notification: Product manufactured in Louisiana and is new to the market.

The intended device is similar in intended use, material, safety and effectiveness in similar applications to: CEFLA s.l.r.'s MyRay K061114, Air Technique's Accent K050693, and Julie Alliance's QuickRay DSX 730 K990002.

The device is to be distributed by Dentron Systems, LLC in the United States.

The following voluntary standards are utilized in whole or in part:

UL 60601-1:2003, Medical Electrical Equipment, Part 1: General Requirements for Safety and Canadian deviations – see IMQ S.p.A. Test report n° 27SE00094 and CSA/UL certificate 231961;

EN 60601-1-2: 2001 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Test, See IMQ S.p.A Test report n° 80SF00347/1 and 80SF000347/2; and

IEC 60601-1-4: 2000 Medical Electrical Equipment – Part 1-4: General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems, See IMQ S.p.A Test report n° 27SE00094.

The materials in the device are identical to materials used in the identified predicate device.

Comparison of the Dentron Sensor to the legally marketed predicate devices:



Discovery



Comparison Table	Dentron Senso	MyRay WDS	Accent	QuickRay
K#	TBD	K061114	K050693	K990002
Intraoral Sensor	CCD + fiber optic plate + scintillator	CCD + fiber optic plate + scintillator	CCD + scintillator	CCD + scintillator
Sensor size (active area)	Size 1: 30x20mm Size 2: 34x24mm	Size 1: 20x30mm Size 2: 24x34mm	Size 1: 20x30mm Size 2: 27.5x36.08mm	21.4x34mm
Sensor cable connection	Sealed at the factory	sealed at the factory	Sealed at the factory	Sealed at the factory
Theoretical resolution	10 lp/mm	25 lp/mm	22.7 p/mm	23.8 lp/mm
Digitalization / Conversion	12 bits (4095 ADU)	12 bit, 4096 grey levels	12 bit, 4096 grey levels	12 bit, 4096 grey levels
Resolution	Wired, USB to CCU	Wireless, Bluetooth	Wireless, Bluetooth	Wired, USB to CCU
Connection	CCU with USB cable	USB-Bluetooth adapter	USB-Bluetooth adapter	CCU with USB cable
Connection medium	Greyscale	Greyscale, TWAIN compatible	Greyscale, TWAIN compatible	Greyscale, Proprietary
Image file format	Powered through USB connection	3xAA rechargeable batteries	4xAA rechargeable batteries	Power applied to CCU only via 12V power adapter
Power supply	No	No	No	No
Sterile product	Existing Commercial software (not part of the device). DentalEye 510k #K012439	Commercial software (not part of the device)	Commercial software (not part of the device)	Commercial software (not part of the device)
File capturing, management and storage		P III 800MHz, Windows XP, 256k RAM, 150M HDU, USB2port, 1024x768x16million color display	Intel P IV 2.8 GHz, Windows XP pro, 1G RAM, 120G HDU, USB 1.1 port, 1024x768x16million color display	P III 600MHz, Windows 98SE, XP 128K RAM, 10G HDU, 2 x USB ports (unspecified), 1024x768x16million color display
PC minimum environment	Windows 2000 / XP			

- concise summary for any performance testing in the submission
- The proposed and predicated devices use similar components and are similar in design, technical characteristics and mode of operation. All the systems include a scintillator coupled to a digital image sensor, electronic circuits to analyze the digital image and transmit the digital image to a personal computer for viewing and further management of the file. The proposed and predicated devices are substantially equivalent, similar devices that have been used by dentists in the US since 1989 and well accepted.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Dentron Systems, LLC
% Mr. Claude D. Berthoin
President/Owner
Video Dental Concepts, Inc.
11 East Granada Boulevard, Suite 207
ORMOND BEACH FL 32176

AUG 23 2013

Re: K080738

Trade/Device Name: Dentron Sensor
Regulation Number: 21 CFR 872.1810
Regulation Name: Intraoral source x-ray system
Regulatory Class: II
Product Code: EAP and MQB
Dated: March 13, 2008
Received: March 18, 2008

Dear Mr. Berthoin:

This letter corrects our substantially equivalent letter of May 13, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

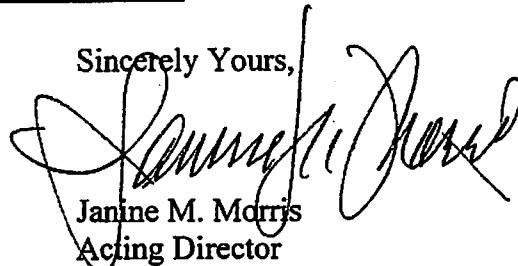
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

INDICATION FOR USE

Applicant: Video Dental Concepts, Inc..

510(k) Number (if known): K080738

Device Name: Dentron Sensor

Indication For Use: The CCD area image sensor is intended to capture an intraoral x-ray image, when exposed to x-rays, for dental diagnostic purposes.

Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

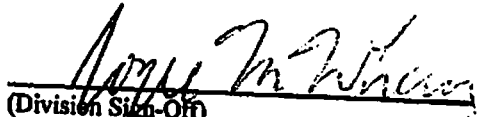
Over the Counter Use _____
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED).

Concurrence of CDRH, Office of Device Evaluation (ODE).

Division Sign-Off
Office of Device Evaluation

510(k) _____


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K080738